DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 9 2005

Ms. Carroll Martin
Regulatory Affairs Generalist
Invacare Corporation
One Invacare way
Elyria, Ohio 44035-4190

Re: K042483
Trade/Device Name: Invacare Pro Nebulizer, Invacare Compact Nebulizer, Invacare Portable Desktop Nebulizer
Regulation Number: 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: December 1, 2004
Received: December 1, 2004

Dear Ms. Martin:

This letter corrects our substantially equivalent letter of December 1, 2004 regarding the trade name.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

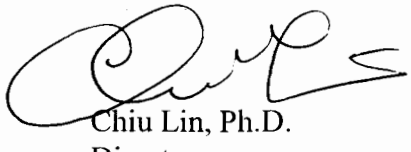
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042483

Device Name: Invacare Pro Nebulizer
Invacare Compact Nebulizer

Indications for Use:

The intended use of the Invacare Pro Nebulizer and the Invacare Compact Nebulizer is to spray liquids in aerosol form into gases that are delivered directly to adult or pediatric patients who have been prescribed inhalation therapy or medication.

The Invacare Pro Nebulizer and Compact Nebulizer are indicated for use with any commercially available nebulizer and mouthpiece.

The Invacare Pro Nebulizer and Compact Nebulizer are intended for home health care use.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K042483

Indications for Use

510(k) Number (if known): K042483

Device Name: Invacare Portable Desktop Nebulizer

Indications for Use:

The intended use of the Invacare Portable Desktop Nebulizer is to spray liquids in aerosol form into gases that are delivered directly to adult or pediatric patients who have been prescribed inhalation therapy or medication.

The Invacare Portable Desktop Nebulizer is used exclusively with its own nebulizer and mouthpiece.

The Invacare Portable Desktop Nebulizer is intended for home health care use.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number K042483

JAN - 6 2005

510(K) SUMMARY FOR INVACARE CORPORATION'S PRO, COMPACT AND PORTABLE DESKTOP NEBULIZERS

This summary of 510(k) safety and effectiveness information is being supplied in accordance with the requirements of the SMDA of 1990 and 21 CFR 807.92

The assigned 510(k) number is K042483.

Date: September 9, 2004

Submitted by: Invacare Corporation
One Invacare Way
Elyria, Ohio 44035-4190

Telephone: 440-329-6356
Fax: 440-326-3607

Contact Person: Carroll L. Martin, Regulatory Affairs Generalist

Trade Name: Invacare Pro
Invacare Compact
Invacare Portable Desktop

Common Name: Nebulizer

Classification Name: Nebulizer (Direct Patient Interface)

Legally Marketed Predicate Device(s): 56 Series Aerosol Generator, K980074, June 12, 1998
Transneb Compressor w/Nebulizer, Model 5000, K032170, May 28, 2004

Device Description:

Invacare Pro Nebulizer: The Invacare Pro Nebulizer is a lightweight, self-contained basic aerosol compressor system intended to provide compressed air to a nebulizer mouthpiece. It is designed to operate with any commercially available, small volume disposable nebulizer mouthpiece.

The Invacare Pro Nebulizer supplies pressurized air to the nebulizer mouthpiece. A small piston air compressor provides the compressed air necessary to drive the nebulizer. The Invacare Pro Nebulizer has a maximum output pressure of 39 psi. The maximum flow rate is 8.5 LPM and the operating flow rate is 4.8 LPM @ 16 psi. Air is drawn into the compressor through a filter and exits the unit through a barbed tubing connection. The compressor is kept cool by drawing air across the motor coil using an integral fan.

A permanently attached mains power cord supplies AC power for the unit and power is controlled by the use of an ON/OFF switch. The motor incorporates a current/temperature overload protector, which

opens the electrical circuit in the event of high current draw or high temperature in the motor winding. The casing for the unit is constructed of ABS flame retardant material.

Invacare Compact Nebulizer: The Invacare Compact is a smaller version of the Invacare Pro. It is a lightweight, self-contained basic aerosol compressor system intended to provide compressed air to a nebulizer's mouthpiece. It is designed to operate with any commercially available, small volume disposable nebulizer mouthpiece.

The Invacare Compact Nebulizer supplies pressurized air to the nebulizer mouthpiece. A small piston air compressor provides the compressed air necessary to drive the nebulizer. It has a maximum output pressure of 33 psi. The maximum flow rate is 8 LPM and the operating flow rate is 4.0 LPM @ 16 PSI. Air is drawn into the compressor through a filter and exits the unit through a barbed tubing connection. The compressor is kept cool by drawing air across the motor coil using an integral fan.

A permanently attached mains power cord supplies AC power for the unit and power is controlled by the use of an ON/OFF switch. The motor incorporates a current/temperature overload protector, which opens the electrical circuit in the event of high current draw or high temperature in the motor winding. The casing for the unit is constructed of ABS flame retardant material.

Invacare Portable Desktop Nebulizer: The Invacare Portable Desktop Nebulizer system consists of a nebulizer and a DC powered piston-type compressor that generates compressed air. Small, lightweight and designed for convenience, the Invacare Portable Nebulizer device offers the user a choice of running off of AC power via a universal adapter or DC power via a 12 volt auto adapter or an optional rechargeable battery pack.

The compressor unit consists of a motor driven piston compressor, printed circuit board and a switch. The circuit board does not incorporate a microprocessor, but serves as a means to prevent double feed of power. This is a safety feature that allows power draw from either the battery or the input adapter, but not both. There is a thermistor incorporated into the circuit board that provides protection by opening the electrical circuit in the event of high motor temperature. The circuit board is not part of the charging circuit for the battery pack. The unit has a maximum pressure of 36 psi and an operating pressure of 10 psi. The maximum flow rate is 5.2 LPM and the operating flow rate is 2.5 LPM @ 10 psi.

The nebulizer mouthpiece employs a venturi effect to convert the medication into a fine aerosol mist. It is used with an extension tube. The nebulizer mouthpiece has a particle size range of ~ 5 microns and a capacity of 7 ml (cc). Providing a connection between the compressor outlet and the nebulizer mouthpiece bottom, the extension tube allows the user to place the compressor on a sturdy surface and to simply hold onto the nebulizer mouthpiece. The nebulizer mouthpiece is designed for single patient use, is reusable and intended to be used exclusively with the Invacare Portable Desktop Nebulizer. Use of the nebulizer mouthpiece, compressor or tubing with other compressors, nebulizer mouthpieces or tubing may produce incorrect flow resulting in improper treatment.

Intended Use: The intended use of the Invacare Pro Nebulizer and the Invacare Compact Nebulizer is to provide compressed air in order to operate a nebulizer for the production of medical aerosol for respiratory disorders. These units require a nebulizer mouthpiece and medication for operation. The use of the Invacare Pro Nebulizer and the Invacare Compact Nebulizer is for the sole purpose of compressed air production.

The Invacare Portable Desktop Nebulizer includes a DC powered air compressor that provides a source of compressed air for home health care use. The compressor is used exclusively with a venturi (pneumatic nebulizer mouthpiece) to convert certain inhaled drugs into an aerosol form for inhalation by a patient.

All of these devices are single-person use, non-sterile, prescription use devices. None of them contain software nor are they intended to be life-supporting or life-sustaining.

Substantial Equivalence: The Invacare Compact Nebulizer is exactly the same unit in design, intended use, safety and performance specifications as the 56 Series Aerosol Generator cleared by FDA for another company under 510(k) accession number K980074 on June 12, 1998. The Invacare Portable Desktop Nebulizer is exactly the same unit in internal operating components, intended use, safety and performance specifications as the Transneb Compressor w/Nebulizer, Model 5000, cleared by FDA, also for another company, under 510(k) accession number K032170 on May 28, 2004. It does have a different outer casing for cosmetic marketing reasons. The Invacare Pro Nebulizer, to be a larger version of the Invacare Compact Nebulizer, is similar in design, intended use, safety and performance specifications as the 56 Series Aerosol Generator, cleared under 510(k) accession number K980074 on June 12, 1998. Medel S.p.A., Italy, registration number 3003826420, manufactures all of these products, including the predicate devices.

Performance Testing: Particle size testing was performed for the Invacare Compact, Pro and Desktop Portable. For this testing, three separate samples of the Compact and Pro with nine different nebulizer/mouthpieces (Turbostream Disposable, Turbostream Reusable, Sidestream Disposable, Sidestream Reusable, Salter 8900, Salter 8960, Medjet Disposable, Medjet Pro, Pari LC Jet Reusable and the Westmed Vix One) were run along with Budesonide, Albuterol and Beclometasone Dipropionate (BDP) as the substances to be nebulized. The same method was used for the Invacare Portable Desktop with the exception that the nebulizer/mouthpiece (Clenny) used is the one that is exclusive to the Invacare Portable Desktop.

Flow/Pressure testing was performed for the Invacare Compact, Pro and Desktop Portable. For this testing, three separate samples of the Compact and Pro were run with the MedelJet nebulizer/mouthpiece and the flow characteristic graphed for each device sample. For the Invacare Portable Desktop, the same method was used with the exception that the neublizer/mouthpiece used was the one that is exclusive to the Invacare Portable Desktop (Clenny).

Compressor nebulization rate testing was also performed for each device. For the Invacare Compact and Pro, three different samples of each device were run with the ten aforementioned nebulizers and three chemicals. For the Portable Desktop, testing was performed with its exclusive nebulizer/mouthpiece (Clenny) and sodium chloride (NaCl) in accordance with EN 13544:2001.

In all instances, each of these devices performed according to specification and functioned as intended.

Performance Standards: These nebulizers have been designed and built in accordance with the applicable requirements of IEC 60601-1-2:2001, EN60601-1:1998, ISO 10993:1999, EN 13544:2001, UL 1431, *UL 2601-1, applicable sections of IEC 801, CISPR 11 Class B, CSA 22.2 No.68 and the FDA November 1993 Reviewer's Guidance for Respiratory Devices.

Note: the UL 2601-1 standard is for the adapter used with the Invacare Portable Desktop Nebulizer. The adapter is a step-down transformer and is governed by this standard.